IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALCON RESEARCH, LTD., Plaintiff, v. BARR LABORATORIES INC., et al., Defendants.	: : : : : : :	CIVIL ACTION NO. 09-CV-0318-LDD

MEMORANDUM CONSTRUING DISPUTED CLAIM TERMS OF U.S. PATENT NOS. 5,631,287; 6,011,062; 6,503,497; AND 6,849,253

Legrome D. Davis, J. September 6, 2011

I. BACKGROUND

This patent infringement action was initiated by Plaintiff Alcon Research, Ltd. ("Alcon") in response to Defendants Par Pharmaceutical, Inc. and Barr Laboratories, Inc.'s (collectively "Defendants") Abbreviated New Drug Applications (ANDA) for FDA approval to market generic versions of Alcon's Travatan® and Travatan Z® products. Travatan® and Travatan Z® are topical prescription eye drops that are used to treat glaucoma and ocular hypertension. The main difference between the two products is that Travatan Z® does not contain a conventional antimicrobial preservative that could, among other things, cause irritation in the eye.

Alcon contends that Defendants' generic versions of Travatan® and Travatan Z® infringe four of Alcon's patents. Two of these patents—No. 5,631,287 ("the '287 patent"), and No. 6,011,062 ("the '062 patent") (collectively the "Schneider patents")—relate to methods of enhancing the chemical stability of travoprost, which is the active ingredient in Travatan® and Travatan Z®. Travoprost is a chemical that belongs to a family of compounds known as prostaglandins. Prostaglandins are highly potent, chemically unstable compounds with low

water solubility. The invention of the Schneider patents involved the discovery that a particular class of surfactants—polyethoxylated castor oils—could be used to improve the chemical stability of prostaglandins in aqueous compositions. Claim 1 of the '287 patent recites:

> A method of enhancing the chemical stability of an aqueous composition comprising a therapeutically effective amount of a prostaglandin, wherein the method comprises adding a chemically-stabilizing amount of a polyethoxylated castor oil to the composition.

'287 patent, col. 8, ll. 57-61 (Pl.'s Ex. 1).

The parties disagree on the meaning of several of the terms used in this claim, and throughout the claims of the Schneider patents, including: (1) "prostaglandin"; (2) "enhancing the chemical stability" / "chemically stabilizing amount"; (3) "therapeutically effective amount"; and (4) "aqueous composition."

The second two patents at issue—No. 6,503,497 ("the '497 patent") and No. 6,849,253 ("the '253 patent") (collectively the "Chowhan patents")—relate to aqueous ophthalmic compositions comprising a certain weight percentage of "borate-polyol complex" having a certain molar range. The invention of the Chowhan patents is directed at enhancing the antimicrobial activity of a solution, and thus reducing or eliminating the need for a conventional ophthalmic preservative. Claim 1 of the '497 patent recites:

> An aqueous ophthalmic composition comprising 0.5 to 6.0 wt. % of a water-soluble borate-polyol complex to enhance the antimicrobial activity of the composition, and water, said complex containing borate and polyol in a molar ratio of 1:0.1 to 1:10.

'497 patent, col 11, ll. 1-5 (Pl.'s Ex. 3). Claim 17 of the '497 patent recites:

> An aqueous ophthalmic composition according to any one of claims 1 to 7, wherein the composition further comprises a preservative effective amount of an ophthalmically acceptable antimicrobial agent.

('497 patent, col 11, ll. 57-60 (Pl.'s Ex. 3).)

The parties disagree on the meaning of several of the terms as used in these claims, and throughout the claims of the Chowhan patents, including: (1) "borate-polyol complex"; (2) "ophthalmically acceptable antimicrobial agent" / "unpreserved"' (3) "enhance the antimicrobial activity"; and (4) "aqueous ophthalmic composition."

The parties seek construction of each of the disputed claims in the Schneider and Chowhan patents. The Court held a claim construction hearing on April 27, 2011. We have reviewed the claims, specification, prosecution history, and other relevant evidence, and have considered the briefing and arguments of the parties. We now construe the terms at issue.

II. STANDARD OF LAW

Claim construction is a question of law to be determined by the court. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995). In its en banc decision in Phillips v. AWH, Corp., 415 F.3d 1303 (Fed. Cir. 2005), the Federal Circuit set forth the legal principles underlying claim construction. That case involved the construction of the term "baffles" as recited in the claims of a patent directed at modular, steel-shell panels that can be welded together to form vandalism-resistant walls. Id. at 1309. The Federal Circuit specifically identified the legal question before it as: "the extent to which [the court] should resort to and rely on a patent's specification in seeking to ascertain the proper scope of its claims." Id. at 1312. In addressing this question, the Phillips court explained how each type of evidence should be used by courts in determining how a person having ordinary skill in the art would understand a disputed claim term. See, generally, id. at 1314–17. Although court reemphasized its prior position that claim terms are "generally given their ordinary and customary meaning" as they

would mean "to a person of ordinary skill in the art in question at the time of the invention," id. at 1313-14 (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)), the Phillips court stressed the importance of recognizing that the person of ordinary skill in the art "is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Phillips, 415 F.3d at 1313. Ultimately, the court's decision allotted far greater weight to the intrinsic record—the claims themselves, the remainder of the specification, and the prosecution history—than to extrinsic evidence such as dictionary definitions and expert testimony. The court quoted its prior pronouncement in Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1478 (Fed. Cir. 1998) that "the best source for understanding a technical term is the specification from which it arose, informed, as needed, by the prosecution history." Phillips, 415 F.3d at 1315 (quoting Multiform Desiccants, 133 F.3d at 1478). "While extrinsic evidence 'can shed useful light on the relevant art,' . . . it is 'less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" Phillips, 415 F.3d at 1317 (quoting C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 862 (Fed. Cir. 2004) and Vanderlande Indus. Nederland BV v. Int'l Trade Comm'n, 366 F.3d 1311, 1318 (Fed. Cir. 2004)). Indeed, "extrinsic evidence cannot be used to vary the meaning of the claims as understood based on a reading of the intrinsic record." Phillips, 415 F.3d at 1319.

In drawing its conclusions, the first source of evidence the Phillips court considered was the language of the claims of the patent. Id. at 1314. "To begin with," the court stated, "the context in which a term is used in the asserted claim can be highly instructive." Id. Using an example taken from the claim language at issue, the Federal Circuit observed that "the claim in

this case refers to 'steel baffles,' which strongly implies that the term 'baffles' does not inherently mean objects made of steel." Id. The court noted that its cases "provide numerous similar examples in which the use of a term within the claim provides a firm basis for construing the term. Id. (citing Mars, Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1374 (Fed. Cir. 2004) (claim term "ingredients" construed in light of the use of the term "mixture" in the same claim phrase); Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1356 (Fed. Cir.1999) (claim term "discharge rate" construed in light of the use of the same term in another limitation of the same claim)). The court stated that other claims of the patent in question, and differences between claims, can also be "valuable sources of enlightenment as to the meaning of a claim term." Id.

The court next considered the role of the "descriptive part" of the specification in claim construction. Id. at 1315. "The claims," the court stated, "do not stand alone. Rather they are part of a 'fully integrated written instrument,' [and] 'must be read in view of the specification, of which they are part.'" Id. (quoting Markman, 52 F.3d at 978-979). In emphasizing the importance of the specification, the court noted that "the specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" 415 F.3d at 1315 (quoting Vitronics, 90 F.3d at 1582). To support its position as to the importance of the specification in claim term construction, the Phillips court cited extensive Supreme Court and Federal Circuit case law, as well as "the statutory directive that the inventor provide a 'full' and 'exact' description of the claimed invention." Id. at 1315-16 (citing Hogg v. Emerson, 47 U.S. (6 How.) 437, 482 (1848) (The specification is a "component part of the patent" and "is as much to be considered with the [letters patent] in construing them, as any paper referred to in a deed or other contract."); Bates v. Coe, 98 U.S. 31,

38 (1878) ("[I]n case of doubt or ambiguity it is proper in all cases to refer back to the descriptive portions of the specification to aid in solving the doubt or in ascertaining the true intent and meaning of the language employed in the claims."); White v. Dunbar, 119 U.S. 47, 51 (1886) (The specification is appropriately resorted to "for the purpose of better understanding the meaning of the claim."); Schriber-Schroth Co. v. Cleveland Trust Co., 311 U.S. 211, 217 (1940) ("The claims of a patent are always to be read or interpreted in light of its specifications."); United States v. Adams, 383 U.S. 39, 49 (1966) ("[I]t is fundamental that claims are to be construed in the light of the specifications and both are to be read with a view to ascertaining the invention."); Markman v. Westview Instruments, Inc., 517 U.S. 370, 389 (1996) ("[A claim] term can be defined only in a way that comports with the instrument as a whole."); Merck & Co. v. Teva Pharms. USA, Inc., 347 F.3d 1367, 1371 (Fed. Cir. 2003) ("A fundamental rule of claim construction is that terms in a patent document are construed with the meaning with which they are presented in the patent document. Thus claims must be construed so as to be consistent with the specification, of which they are a part."); Netword, LLC v. Centraal Corp., 242 F.3d 1347, 1352 (Fed. Cir .2001) ("The claims are directed to the invention that is described in the specification; they do not have meaning removed from the context from which they arose."); 35 U.S.C. § 112, ¶ 1).

Consistent with these principles, the court reaffirmed that an inventor's own lexicography and any "intentional disclaimer, or disavowal of claim scope" are dispositive. Id. On this point, the court stated that "the specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." Id. at 1321 (quoting Vitronics, 90 F.3d at 1582; and citing Irdeto Access, Inc. v. Echostar Satellite Corp., 383 F.3d 1295, 1300 (Fed. Cir.

2004) ("Even when guidance is not provided in explicit definitional format, the specification may define claim terms by implication such that the meaning may be found in or ascertained by a reading of the patent documents.") After considering the way in which the Patent and Trademark Office interprets claims, and determining that this provides further support for placing great weight on the specification in construing claim terms, the court concluded: "[i]t is therefore entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." Id. at 1317.

The Phillips court next provided a brief explanation of the prosecution history's utility in construing claim terms. The court noted that "[l]ike the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent," id., and it reaffirmed its prior position that "the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." Id. (citing Vitronics, 90 F.3d at 1582–83).

Finally, the Federal Circuit limited the weight of extrinsic evidence—i.e., expert and inventory testimony, dictionaries and learned treatises—in claim construction. In so doing, the court rejected the "dictionaries first" method set down by a prior three-judge panel of the Federal Circuit in Texas Digital Systems, Inc. v. Telegenix, Inc., 308 F.3d 1193 (Fed. Cir. 2002). See Phillips, 415 F.3d at 1329 (Laurie, J., dissenting) (noting "the court now has decided not to follow" the "'dictionaries first' procedure."). Under the Texas Digital approach, the construing court was first to look to texts—dictionaries, encyclopedias, treatises—to ascertain the ordinary, objective meaning of a term. Texas Digital, 308 F.3d at 1202; see also Kumar v. Ovonic Battery

Co., Inc., 351 F.3d 1364, 1367 (Fed. Cir. 2003) ("Under our precedent in Texas Digital . . . we look first to the dictionary definition of a contested term."). Then, "because words often have multiple dictionary meanings, the intrinsic record must be consulted to determine which of the possible dictionary meanings is most consistent with the use of the term in question by the inventor." Phillips, 415 F.3d at 1319 (discussing the Texas Digital approach). If more than one dictionary definition is consistent with the intrinsic record, "'the claim terms may be construed to encompass all such meanings.'" Id. (quoting Texas Digital, 308 F.3d at 1203.) However, the en banc court stated in Phillips that "[i]n effect, the Texas Digital approach limits the role of the specification in claim construction to serving as a check on the dictionary meaning of a claim term . . . . " Id. at 1320. "The main problem with elevating the dictionary to such prominence," the Phillips court stated, "is that it focuses the inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent. Properly viewed, the 'ordinary meaning' of a claim term is its meaning to the ordinary artisan after reading the entire patent." Id. at 1320. Therefore, the Texas Digital approach "improperly restricts the role of the specification in claim construction." Phillips, 415 F.3s at 1320.

Ultimately, the court concluded that extrinsic evidence was less reliable than intrinsic evidence, reasoning as follows:

> First, extrinsic evidence by definition is not part of the patent and does not have the specification's virtue of being created at the time of patent prosecution for the purpose of explaining the patent's scope and meaning. Second, while claims are construed as they would be understood by a hypothetical person of skill in the art, extrinsic publications may not be written by or for skilled artisans and therefore may not reflect the understanding of a skilled artisan in the field of the patent. Third, extrinsic evidence consisting of expert reports and testimony is generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence . . . . Fourth, there is a virtually unbounded universe of potential extrinsic evidence of some marginal relevance that could be

> brought to bear on any claim construction question . . . . Finally, undue reliance on extrinsic evidence poses the risk that it will be used to change the meaning of claims in derogation of the indisputable public records consisting of the claims, the specification and the prosecution history, thereby undermining the public notice function of patents.

Id. at 1318-19 (internal citations and quotation marks omitted). Therefore, "while extrinsic evidence can shed useful light on the relevant art, . . . it is less significant than the intrinsic record in determining the legally operative meaning of claim language. " Id. 415 F.3d at 1317 (internal citations an quotation marks omitted).

With these clearly-articulated legal principles guiding us, we now construe each of the claims terms at issue in the present dispute.

III. DISCUSSION[1]

A. The Chowhan Patents

1. Borate-Polyol Complex

The parties disagree as to the meaning of the term "borate-polyol complex" as it is used within the '497 and '253 patents. Alcon's proposed construction is: "A mixture of borate and polyol in aqueous solution." (Pl.'s Opening Br. at 25.) Defendants' proposed construction is: "A compound which is formed by the reaction of borate and polyol, wherein the polyol molecule is bonded to a central borate atom." (Def.s' Opening Br. at 14.) Relying heavily on the context in which the term is used within the claims themselves, we adopt Alcon's definition.

In their opening brief, Defendants base their construction of "borate-polyol complex" on

[1]We consider the claims in the order they were presented in the Markman hearing on April 27, 2011. Argument on the first term, "borate-polyol complex," occupied a majority of the time at the hearing and the most significant portion of the parties' briefs. Accordingly, it commands the bulk of our treatment in this Memorandum as well.

their expert's opinion as to the meaning of the term, and an example of an interaction between borate and polyol as depicted in a mouth wash formulation that appeared in the treatise Remington's Pharmaceutical Sciences in 1980. (Def.s' Opening Br., Doc. No. 147 at 14-15 (citing Decl. of Professor Richard Pizer, Doc. No. 150, and Remington's Pharmaceutical Sciences at 1445 (Mack Publishing Co. 1980) ("Remington's").) Defendants begin their discussion of the term by stating: "[c]hemical complexes are understood by persons of ordinary skill to be a molecular entity in which a central atom[] is bonded to two or more moities, which may be ions, atoms, or molecules (also called ligands)." (Def.s' Opening Br. at 14.) Defendants cite their retained expert, Professor Richard Pizer, for this proposition. (Def.s' Opening Br. at 14.) A review of Professor Pizer's declaration reveals his opinion as to the general definition of the term "borate-polyol complex." (Pizer Decl., Doc. No. 150 at ¶ 16). The definition he provides for the term is identical to Defendants' proposed definition. (Pizer Decl., Doc. No. 150 at ¶ 12.)

After setting out their initial definition, Defendants then explain why this definition is consistent with the description in the '479 and '253 patents. Defendants' state:

> According to the specification of the Chowhan patents "[t]he water-soluble borate-polyol complexes of the present invention may be formed by mixing borate with the polyol(s) of choice in an aqueous solution." A person of skill in the art would understand that when borate and polyol are mixed in an aqueous solution, a chemical reaction takes place to form one or more new molecular species, referred to as borate polyol complexes, where the central atom (boron) is bonded to one or more polyol moities.

(Def.s' Opening Br. at 15 (citing Pizer Decl. and "Remington's".)

Alcon, on the other hand, focuses on the language in the specification and the claims themselves that the borate polyol-complexes contain "a molar ratio of borate to polyol

[]generally between about 1:0.1 and about 1:10, and [] preferably between about 1:0.25 and about 1:2.5." (Alcon's Opening Br., Doc. No. 145 at 20 (citing '497 patent, col 3, ll. 31-33).) "Importantly," Alcon states,

> there is absolutely no mention of whether the borate and the polyol chemically combine in such ratios—this information is not important to practicing the invention or determining whether claims are infringed. In fact, the specification makes clear that "complex" does not refer to a chemical combination because borate and polyol cannot chemically combine in the various claimed ratios within the range of 1:0.1 to 1:10.

(Pl.'s Opening Br. at 20-21.) Alcon then relies on statements made by the inventor during the prosecution of the patents regarding the amounts of borate and polyol which, Alcon argues, makes clear that the inventor "did not mention doing any complicated analytical chemistry to determine how many molecules reacted with other molecules of polyol; rather he clearly and simply added up the total borate and total polyol added to create the solution." (Pl.'s Opening Br. at 23.) Accordingly, the argument goes, "borate-polyol complex" refers to the "combination of all the borate and all the polyol that were present in the solution, without regard to how much, if any, chemically bonded to each other." (Pl.'s Opening Br. at 23.)

In determining the proper construction of this term, we look first, as the Federal Circuit did in Phillips, to the language of the claim itself. 415 F.3d at 1324-25. Claim 1 of the '497 patent recites:

> An aqueous ophthalmic composition comprising 0.5 to 6.0 wt. % of a water-soluble borate-polyol complex to enhance the antimicrobial activity of the composition, and water, said complex containing borate and polyol in a molar ratio of 1:0.1 to 1:10.

('497 patent, col 11, ll. 1-5 (Pl.'s Ex. 3).) As educated laymen, we recognize that a "composition comprising . . . borate-polyol complex . . . and water" describes some sort of aggregate

combination of borate and polyol and water. Whether "borate-polyol complex" means that borate and polyol must form a "compound" or a "new molecular species," as Defendants argue, or whether borate and polyol may exist side-by-side in a "mixture," irrespective of any interaction between them, as Alcon argues, is not clear to us from the face of the term alone. The Phillips court, however, found key insights as to the meaning of the term "baffles" through the language of the claims themselves. Id. In that case, the court declined to construe the term in a way which would have rendered certain claim language "unnecessary" or "redundant." Id. The court's reasoning here squares with the Federal Circuit's stated rule that "[a]ll the limitations of a claim must be considered meaningful." Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1562 (Fed. Cir. 1991) Adding to this rule of construction, the Federal Circuit has more recently stated that "[a] claim construction that renders asserted claims facially nonsensical 'cannot be correct.'" Becton, Dickinson and Co. v. Tyco Healthcare Group, LP, 616 F.3d 1249, 1255 (Fed. Cir. 2010) (quoting Schoenhaus v. Genesco, Inc., 440 F.3d 1354, 1357 (Fed. Cir. 2006); and Bd. of Regents v. BENQ Am. Corp., 533 F.3d 1362, 1370 (Fed. Cir. 2008) (refusing to adopt a claim construction that "would effect [a] nonsensical result."); see also, Markman, 517 U.S. at 390 (stating that claims are to be construed to "preserve the patent's internal coherence."). In this case, we consider the inherent coaction of the claims, and find that Defendants' construction of "borate-polyol complex" would render a significant portion of the claims patent facially nonsensical and meaningless such that it cannot be correct. Alcon's construction of the term, however, jibes with the rest of the claim language.

The language of claim 1 makes clear that the borate-polyol "complex contain[s] borate and polyol in a molar ratio of 1:0.1 to 1:10." ('497 patent, col 11, ll. 1-5 (Pl.'s Ex. 3).) Extrinsic

evidence provided by both parties "sheds useful light," as it may, see Phillips, 415 F.3d at 1317 ("extrinsic evidence can shed useful light on the relevant art"), on the fact that borate and polyol cannot form compounds at the ends of the molar ratios provided in this claim.[2] Requiring the term "borate-polyol complex" to mean a "compound," as Defendants suggest, while at the same time reciting molar amounts of borate and polyol at which they cannot actually form compounds, would render the range recited in the claim, and the claim itself, nonsensical and incoherent. Therefore, such a construction cannot be correct. Indeed, Defendants' proposed definition—which refers to "*the* polyol molecule" (singular) binding to "*a* central borate atom" (singular)—implies that the borate-polyol complex is limited to a 1:1 molar ratio. Clearly, a borate-polyol complex limited to a 1:1 molar ratio is discordant with a "complex containing borate and polyol in a molar ratio of 1:0.1 to 1:10." Unquestionably, Defendants' proposed

[2]The lead inventor of the '497 and '253 patents, Dr. Chowhan, testified that a single borate molecule may bond chemically with polyol in only two possible ways: in a 1:1 ratio or a 1:2 ratio. (Alcon Rebuttal Br., Doc. No. 165 at 21 (citing Chowhan Decl., Ex. 6).) Defendants' own experiment verifies that, under a formulation described in the patents, bonding occurs in these molar ratios. (See Def.s' Rebuttal Br. at 7 ("The NMR peak at δ = -13.286 corresponds to the borate-polyol complex in a 1:1 molar ratio, and the peak at δ = -9.241 corresponds to the borate-polyol complex in a 1:2 ratio.").) Defendants argue, however, that borate and polyol can form compounds at ratios higher than 1:1 or 1:2 and provide examples of borate and certain polyols reacting at ratios stated as high as 1:3 or 1:4. (See Def.s' Rebuttal Br. at 8 ("For example, mannitol, one of the preferred polyols disclosed by the Chowhan patents . . . has three pairs of adjacent -OH groups, each pair of which has the potential to react with a borate ion."); see also Markman Hr'g Tr. at 86:1-10 (Apr. 27, 2011) ("So, for example, Borax, . . . a common borate used for cleaning . . .would give you a - - a larger say here four to one molar ratio under our construction.").) Although Defendants offer these examples to demonstrate that borate and polyol can interact at ratios higher than 1:1 or 1:2, they do not dispute that there is no known way for borate to bond with polyols such as propylene glycol or sorbital in ratios of 1:01 or 1:10, as claimed in claim 10 of the '253 patent, despite the fact that Alcon raised this point in its rebuttal brief, (Alcon Rebuttal Br., Doc. No. 165 at 21), and at the Markman hearing, (Markman Hr'g Tr. at 90:13-22). We find the extrinsic evidence overwhelmingly demonstrates that borate and polyol cannot form compounds at the ends of the molar ratios provided in the claims.

construction renders the molar range described in the claim meaningless. The interpretation, on the other hand, that "borate-polyol complex" refers to a "mixture," which may contain bonded and unbonded borate and polyol, is entirely consistent with the claim's requirement that the "complex contain[] borate and polyol in a molar ratio of 1:0.1 to 1:10." ('497 patent, col 11, ll. 1-5 (Pl.'s Ex. 3).) Accordingly, we find that the language of the claims themselves is dispositive of the meaning of "borate-polyol complex." By implication, the term means, as Alcon suggests, "a mixture of borate and polyol in aqueous solution." Phillips, 415 F.3d at 1321 ("[T]he specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms *by implication*.") (internal citations and quotation marks omitted) (emphasis added).

Nothing in the descriptive portion of the specification alters this interpretation. In fact, the written description echoes the claims on this issue. Referring to the "water-soluble borate-polyol complexes," the patents state that "[i]n such compositions, the molar ratio or borate to polyol is generally between about 1:01 to 1:10 . . . ." (Pl.'s Opening Br. at 20 (citing '497 patent, col 3, ll. 31-33).) The reasoning we set forth above with regard to this range being nonsensical in light of the binding properties of the molecules applies with equal force here.

In arguing that the written description proves Alcon's interpretation incorrect, Defendants point to one of twelve examples provided in the patent. They argue that adopting Alcon's construction and calculating the weight percentage of borate-polyol complex listed in Example 5 would mean that the weight percentage of the complex was higher than 6%—the claim's upward limit. Defendants rely on the Federal Circuit's holding in Vitronics, which states that a construction putting an embodiment out of the claim scope is usually incorrect. 90 F.3d at

1583. In Vitronics, the court held that if it were to define a claim in a particular way, "a preferred (and indeed only) embodiment in the specification would not fall within the scope of the patent claim. Such an interpretation is rarely, if ever, correct and would require highly persuasive evidentiary support, which is wholly absent in this case." Id. However, in the present case, even if Alcon's construction puts Example 5 out of the claim scope—and based on the fact that the claim is a "comprising" claim, it is not clear that it does—such a finding does not preclude construction of the term in the manner supported by the claims and the other language of the description. Unlike in Vitronics, which featured a single embodiment, in the present case there are eleven other examples, each of which is within range under Alcon's proposed definition. Furthermore, unlike in Vitronics, the present case features highly persuasive evidentiary support for the construction that is potentially at odds with the embodiment. The language of the claim 1 itself, and the fact that it would be rendered nonsensical by any other construction, as discussed above, provides conclusive evidence that the term "borate-polyol complex" refers to "a mixture of borate and polyol in aqueous solution."

If anything, the examples in the patents affirmatively demonstrate Defendants' interpretation to be incorrect. A review of the examples reveals nothing about borate and polyol interacting, or the environmental conditions necessary to achieve such interaction. Indeed, not a single one of the twelve examples offers any indication as to how much borate and polyol have combined on a molecular level such that, if we were to adopt Defendants' definition, we could say with any certainty that the examples are within the 0.5 to 6 wt. % range. Under Defendants' definition, a person seeking to practice this invention would likely have to run an experiment, complete with NMR analysis, to determine whether the recited wt. % range is met. However, it

is a well-established validity requirement that the specification must "enable one of ordinary skill in the art to practice the claimed invention *without undue experimentation*." Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1999). The experimentation required to verify that the amount of borate and polyol compound is within the recited weight percentage could conceivably run afoul of the enablement requirement here. In claim construction, it is a "well-established rule . . . that claims should be interpreted, if possible, so as to preserve their validity. Evans Medical Ltd. v. American Cyanamid Co., 11 F. Supp. 2d 338, 352 (S.D.N.Y. 1998) (citing Amhil Enters. Ltd. v. Wawa, Inc., 81 F.3d 1554, 1561 (Fed. Cir. 1996)). Of course, claims should only be construed to preserve their validity "where the proposed claim construction is practicable, is based on sound claim construction principles, and does not revise or ignore the explicit language of the claims." Generation II Orthotics Inc. v. Medical Technology Inc., 263 F.3d 1356, 1365 (Fed. Cir. 2001). In the present case, unlike Defendants' construction, which leads to a cloudy enablement result, Alcon's construction ensures that no undue experimentation is required to practice the patent such that the claims are adequately enabled, and the validity of the patent is preserved. This proposed claim construction is certainly practicable, as the claims are logical when this meaning is adopted, it is based on sound claim construction principles (in that it is born from the inherent meaning of the claims themselves), and it in no way revises or ignores the explicit language of the claims.

Turning to the prosecution history, we find that the patents' administrative records do not affect the outcome of the analysis here. Indeed, the prosecution history is not needed when the claims themselves and the descriptive part of the specification provide a clear definition. See Phillips, 415 F.3d at 1315 ("The best source for understanding a technical term is the

specification from which it arose, informed, *as needed*, by the prosecution history.") (emphasis added). Nothing in the prosecution history demonstrates that the inventor limited the invention in the course of prosecution, or made the claim scope narrower than it would otherwise be. Id. at 1315. Accordingly, we place little to no weight on the prosecution history of the patent in our determination of the claim term's meaning.

Finally, we end our discussion of this claim term by noting that adopting Defendants' construction of the term would require that we utilize an "extrinsic evidence first" method—a form of which was specifically rejected by the court in Phillips. See, 415 F.3d at 1318-20. Citing their retained expert, Defendants in this case begin their claim construction analysis by stating, generally and abstractly, that "[c]hemical complexes are understood by persons of ordinary skill to be a molecular entity in which a central atom[] is bonded to two or more moities, which may be ions, atoms, or molecules (also called ligands)." (Def.s' Opening Br. at 14.) At the Markman hearing on this term, it was only after a long argument based on extrinsic evidence that Defendants shifted their attention to intrinsic evidence. (See Markman Hr'g Tr. at 73:20-21 (Apr. 27, 2011).) It is clear that Defendants base their interpretation of the claim term on an "extrinsic evidence first" model and request that we adopt their interpretation by doing the same. Under Federal Circuit precedent, however, it would be improper for us to do so. Instead, applying the appropriate weight to the types of evidence presented in this case, we find that, *in the context of this patent*, "borate-polyol complex" has the meaning that Alcon suggests.

2. "Ophthalmically Acceptable Antimicrobial Agent" / "Unpreserved"

The term "ophthalmically acceptable antimicrobial agent" appears in claim 26 of the '497 patent, and claims 5, 9, 14 and 18 of the '253 patent. Alcon contends that the term means a

"conventional ophthalmic antimicrobial preservative," and that the term "unpreserved," as it appears in claims 20, 21, 32, 43, and 45 of the '497 patent, is the mirror image of "ophthalmically acceptable antimicrobial agent"—i.e., "unpreserved" means "lacking an ophthalmically acceptable antimicrobial agent." (Pl.'s Opening Br. at 25.) Defendants construe "ophthalmically acceptable antimicrobial agent" to mean "an agent that is active against microorganisms and that is toxicologically safe for use in the eye." (Def.s' Opening Br. at 21.) They construe "unpreserved" to mean "allows the growth of microorganisms if they gain entry into the formulation and does not include an ingredient specifically for the purpose of preserving the formulation." (Def.s' Opening Br. at 22.) We find that the intrinsic evidence supports Alcon's proposed construction.

Defendants' proposed construction of "ophthalmically acceptable antimicrobial agent" arises from their expert's opinion as to the meaning of the term "ophthalmically acceptable" as it is used in other patents filed by other inventors. (See Def.s' Opening Br. at 21-22, citing Expert Declaration of Michael J. Miller, PhD., Doc. No. 151 ("Miller Declaration").) A review of the Miller Declaration reveals a construction identical to Defendants' proposed construction and an assessment of the teachings of a number of other patents using the term "ophthalmically acceptable" in various contexts. Defendants' construction, however, ignores the intrinsic evidence. That evidence plainly demonstrates that Defendants' definition of the term is incorrect.

The Chowhan patents' specifications make clear that borate itself has inherent antimicrobial activity and is toxicologically safe for use in the eye. The '497 patent states that "[b]orate is the buffer of choice for use in ophthalmic compositions, since it has some inherent

antimicrobial activity . . . ." ('497 patent, col. 1, ll. 33-34 (Pl.'s Ex. 3).) The '253 patent contains the same language. ('253 patent, col. 1 ll. 36-37 (Pl.'s Ex. 4).) Borate, therefore, meets Defendants' definition of an "ophthalmically acceptable antimicrobial agent"—it is active against microorganisms and it is toxicologically safe for use in the eye. Several of the claims of the Chowhan patents, however, specifically require borate while at the same time excluding an "ophthalmically acceptable antimicrobial agent." (See, e.g., '497 patent, claims 19, 28, 39 (Pl.'s Ex. 3); '253 patent, claims 5, 9, 14, 18 (Pl.'s Ex. 4).) Under Defendants' construction, these claims would be nonsensical—it would both require, and exclude, an ophthalmically acceptable antimicrobial agent. As we explained with regard to "borate-polyol complex," above, "[a] claim construction that renders asserted claims facially nonsensical 'cannot be correct.'" Becton, Dickinson and Co., 616 F.3d at 1255. As was the case with the previously construed term, Defendants' reliance on extrinsic evidence and definitions of terms divorced from the context of the patents at issue leads to irreconcilable problems with the scope and logic of the present teachings.

By looking to the intrinsic evidence, we avoid the issues presented by Defendants' abstract definitions. That evidence supports Alcon's construction. Notably, in the Second Preliminary Amendment, filed in April 2002, Alcon stated:

> Claims 25-40 do not recite an ophthalmically acceptable microbial agent as a component of the claimed compositions, but the claims are open to the inclusion of such agents as conventional antimicrobial preservatives. The borate-polyol complexes of the present invention enhance the antimicrobial activity of ophthalmic compositions, independently of whether conventional antimicrobial preservatives, such as those described in lines 9-17 on page 2 (e.g., benzalkonium chloride, polyquaternium-1, etc.), are present. However, in come cases it may be necessary to include a conventional antimicrobial preservative in order to achieve a particular level of antimicrobial activity associated with regulatory requirements for preservative efficacy, or other criteria.

> Conversely, in some cases it is not necessary to include a conventional antimicrobial preservative in order to satisfy regulatory requirements or other criteria. Such embodiments of the invention are now expressly claimed in Claims 43, 44, 45, 52, 56, 63, 67 and 69. Support for these claims is provided by the description of the invention appearing at lines 10-21 on page 4, and by the description of "unpreserved" solutions presented in Example 11 on page 14.

(Second Preliminary Amendment, Pl.'s Ex. 12 at 8, 9.) Claim 43, as specified in this Amendment, recites "[a]n aqueous ophthalmic composition . . . wherein the composition does not contain an *ophthalmically acceptable antimicrobial agent*. (Second Preliminary Amendment, Pl.'s Ex. 12 at 4 (emphasis added).) Claim 45 recites "an aqueous, *unpreserved* ophthalmic solution comprising an amount of a water soluble borate-polyol complex effective to enhance the antimicrobial activity of the solution." (Second Preliminary Amendment, Pl.'s Ex. 12 at 4 (emphasis added).) Accordingly, the claims as recited in the amendment that lack "a conventional antimicrobial preservative" are those that "do[] not contain an ophthalmically acceptable antimicrobial agent" or are "unpreserved." Thus, this aspect of the intrinsic record clearly demonstrates that the terms are analogues—an "ophthalmically acceptable antimicrobial agent" is a "conventional antimicrobial preservative" (e.g., benzalkonium chloride, polyquaternium-1), and a composition is "unpreserved" if it "lacks an ophthalmically acceptable antimicrobial agent."

3. "Enhance the Antimicrobial Activity"

The term "to enhance the antimicrobial activity" is recited in claims 1, 21, 22, and 33 of the '497 patent and claims 1 and 10 of the '253 patent. Alcon's proposed definition is: "to improve the results of preservative efficacy testing by improving the killing of one or more of the microbes that are routinely used in such testing." (Pl.'s Opening Br. at 27.) Defendants define the terms as "to increase / increasing the antimicrobial effectiveness of a formulation

against challenged microorganisms being evaluated in a standardized testing procedure when compared with a baseline or comparable formulation." (Def.s' Opening Br. at 24; Def.s' Rebuttal Br. at 14.) The only point of contention between the parties on this term is whether it allows for worsening with respect to any of the challenged microbes.

Common sense application of the widely accepted meaning of commonly understood words tells us that Alcon's definition is undoubtedly incorrect. Phillips, 415 F.3d at 1314 ("In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.") Under Alcon's definition, a solution could enhance the antimicrobial activity of a formulation if, for example, it killed one strain of challenged microorganism, but caused the condition of all other microbes, including the most clinically dangerous ones, to worsen significantly. Such a result plainly does not represent "enhanced antimicrobial activity." Common sense also tells us, however, that the antimicrobial activity of a solution may be "enhanced" if it shows clinically meaningful improvement on several challenged microbes, but slight worsening on one microbe to a point where the risk posed is not such that it would fail FDA regulatory standards. To this Court, the question of whether a composition has "enhanced the antimicrobial activity" involves a utilitarian calculus that considers the probability and magnitude of the clinical harm posed by each type of microorganism. However, the patent, and the parties in their briefs, do not specify how we should consider such risk. Accordingly, we find that a general definition such as that provided by Defendants—but without the "all" limitation— is appropriate. "To enhance the antimicrobial activity of the composition," therefore, means "to increase / increasing the

antimicrobial effectiveness of a formulation against challenged microorganisms being evaluated in a standardized testing procedure when compared with a baseline or comparable formulation."

4. "Aqueous Ophthalmic Composition"

The parties disagree as to the meaning of the term "aqueous ophthalmic composition" as it appears in claims 1-20 of the '497 patent and claim 17 of the '253 patent. Alcon contends that the term refers to a "composition in which the water-soluble borate-polyol complex is present in the aqueous phase." (Pl.'s Opening Br. at 29.) Defendants contend that the term refers to a composition in which "all of the components collectively are in an aqueous formulation." (Def.s' Rebuttal Br. at 16.) We find that the intrinsic evidence supports the term "aqueous ophthalmic composition" to mean "a composition in which the water-soluble borate-polyol complex is present in the aqueous phase."

Our lay sensibilities tell us that, in general, an "aqueous ophthalmic composition" encompasses a water-based formulation containing components directed toward use in the eye. In the context of the Chowhan patents, however, the term is narrower. Claim 1 of the '497 patent recites:

> An aqueous ophthalmic composition comprising 0.5 to 6.0 wt. % of a water-soluble borate-polyol complex to enhance the antimicrobial activity of the composition, and water, said complex containing borate and polyol in a molar ratio of 1:0.1 to 1:10.

('497 patent, col 11, ll. 1-5 (Pl.'s Ex. 3)). Clearly, as used in this claim, an "aqueous ophthalmic composition" must contain "water-soluble borate-polyol complex." The descriptive portion of the patent specification further directs that "the *water-soluble* borate-polyol complexes of the present invention may be formed by mixing borate with the polyol(s) of choice in an aqueous *solution* . . . ." ('497 patent, col 3, ll. 8-32 (Pl.'s Ex. 3) (emphasis added).) Therefore, the

aqueous ophthalmic compositions of this patent require that the *water-soluble* borate-polyol complexes are dissolved in an aqueous *solution*. The specification also makes clear, however, that the broader "compositions" of the present invention are not limited to solutions. Defendants themselves champion this point. (See Def.s' Opening Br. at 26 ("The 'composition' may be in the form of a solution, suspension, gel, cream, powder, solid, or aerosol."); Def.s' Rebuttal Br. at 16 ("The Chowhan Patents themselves teach that preferred 'compositions' of the claimed invention may be in various forms, 'such as eye drops, gels, or ocular inserts." (citing '497 patent. Col. 3, ll, 52-56)).) The '253 patent contains the same language. ('253 patent, col. 3, ll. 52-53 (Pl.'s Ex. 4).) Therefore, the specification of the Chowhan Patents requires that the "aqueous ophthalmic compositions" of the present invention are either entirely water-based solutions, or other water-based compositions, e.g., emulsions, in which the borate and polyol are dissolved in the aqueous phase. See Phillips, 415 F.3d at 1315 ("[T]he claims themselves provide substantial guidance as to the meaning of particular claim terms.); see also, id. at 1321 ("[T]he specification acts as a dictionary when it . . . defines terms by implication.")

B. The Schneider Patents

1. "Prostaglandin"

The term "prostaglandin" is recited in each asserted claim of the Schneider patents. For example, claim 1 of the '287 patent recites:

> A method of enhancing the chemical stability of an aqueous composition comprising a therapeutically effective amount of a *prostaglandin*, wherein the method comprises adding a chemically-stabilizing amount of a polyethoxylated castor oil to the composition.

('287 patent, col. 8, ll. 57-61 (Pl.'s Ex. 1) (emphasis added).)

The '287 patent expressly defines the term.[3] It begins its definition by stating that "[t]he terms 'prostaglandin' and 'PG' are generally used to describe a class of compounds which are analogues and derivatives of prostanoic acid." ('287 patent, col. 2, ll. 23-25(Pl.'s Ex. 1) (emphasis added).) The specification continues by outlining the molecular structures of these general prostaglandins, before stating:

> The prostaglandins *which may be utilized in the present invention* include all pharmaceutically acceptable prostaglandins, their derivatives and analogues, and their pharmaceutically acceptable esters and salts. *Such prostaglandins include* the natural compounds: PGE_1, PGE_2, PGE_3, $PGF_{1\alpha}$, $PGF_{2\alpha}$, $PGF_{3\alpha}$. PGD_2, and PGI_2 (prostacyclin), as well as analogues and derivatives of these compounds which have similar biological activities of either greater or lesser potencies. Analogues of the natural prostaglandins *include but are not limited to*: alkyl substitutions . . ., which confer enhanced or sustained potency by reducing biological metabolism or alter selectivity of action . . .

('287 patent, col. 3, ll. 46-58 (Pl.'s Ex. 1) (emphasis added).)

The parties' disagreement centers on whether certain language in this definition is lexicographic, as Alcon contends, or merely exemplary, as Defendants argue. Alcon urges us to adopt this definition:

> The natural compounds PGE_1, PGE_2, PGE_3, $PGF_{1\alpha}$, $PGF_{2\alpha}$, $PGF_{3\alpha}$. PGD_2, and PGI_2 (prostacylcin), as well as analogues and derivatives of such natural compounds (including the pharmaceutically acceptable esters and salts of such natural compounds and their analogues and derivatives), which have similar biological activities of either greater of lesser potencies.

(Pl.'s Opening Br. at 14.) Defendants argue for a broad definition based on their position that the language "such prostaglandins include . . ." is merely exemplary—it does not limit the definition of "prostaglandin" as generally set out in the earlier sentence. Accordingly,

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[3]The '287 and '062 patents contain identical language with respect to the definition of "prostaglandin."

Defendants insert the "e.g." qualifier into their definition:

> Any analogue or derivative of prostanoic acid, including any pharmaceutically acceptable ester thereof, natural prostaglandins (e.g., PGE_1, PGE_2, PGE_3, $PGF_{1\alpha}$, $PGF_{2\alpha}$, $PGF_{3\alpha}$. PGD_2, and PGI_2) and analogues and derivative of those compounds.

(Def.s' Opening Br. at 6.)

We find, however, that the language at issue is not merely exemplary, but that it is intended to be lexicographic and expressly constrains the definition of the term prostaglandin within the context of these patents. Phillips, 415 F.3d at 1321 ("[T]he specification acts as a dictionary when it expressly defines terms used in the claims. . . . ."); E-Pass Technologies, Inc. v. 3Com Corp., 343 F.3d 1364, 1369 (Fed. Cir. 2003) ("[I]n determining whether a statement by a patentee was intended to be lexicographic, it is important to determine whether the statement was designed to define the claim term or to describe a preferred embodiment.") Four aspects of the patents lead us to this conclusion. First, in specifying the prostaglandins that may be used in the present invention as "the natural compounds . . . and analogues and derivatives of these compounds which have similar biological activities," the patents use the term "include" without the modifier "but are not limited to." ('287 patent, col. 3, ll. 50 (Pl.'s Ex. 1) (emphasis added).) In the very next sentence of the definition, when discussing the acceptable analogues, the '287 patent uses the language "including *but not limited to*." ('287 patent, col. 3, ll. 55 (Pl.'s Ex. 1) (emphasis added).) The fact that the patent drafter in one sentence used the language "including," and the very next sentence "including but not limited to," suggests to us that the former sentence sets forth an express closed-ended definition, and not merely potential embodiments or examples. Second, a review of the patents reveals that where they intend to indicate exemplary language, they do so clearly. For example, the patents provide "*examples* of

prostaglandins which are useful in the present invention," ('287 patent, col. 4, ll. 11-12 (Pl.'s Ex. 1) (emphasis added), "*examples* of suitable agents which may be utilized to adjust the tonicity or osmolality of the formulations," ('287 patent, col. 6, ll. 54-56 (Pl.'s Ex. 1) (emphasis added), and "*examples* of table buffering agents," ('287 patent, col. 6, ll. 54-56 (Pl.'s Ex. 1) (emphasis added). They do not label the "natural compounds . . . and analogues and derivatives of these compounds which have similar biological activities" as "examples" of the prostaglandins that could be used in the present invention, as they do elsewhere. Third, the nature of the language itself suggests to us that it is not merely exemplary. The language in question contains an "as well as" conjunction. The phrasing "A, B, and C, *as well as* D"suggests to us a complete, as opposed to an open-ended or exemplary, set. Finally, Defendants have not convinced us that any of the embodiments of the invention are put outside the scope of the claims if we adopt Alcon's construction. Although Defendants "don't believe that Compounds 2 and 3 are compounds of the D Series," (Markman Hr'g Tr. at 154:5-6 (Apr. 27, 2011), they have not provided any evidence to convince us that the compounds are not acceptable analogues with similar biological activities such that they meet Alcon's definition. Accordingly, we find that the expressly narrowed definition of "prostaglandin" for the purposes of the Schneider Patents is:

> The natural compounds PGE_1, PGE_2, PGE_3, $PGF_{1\alpha}$, $PGF_{2\alpha}$, $PGF_{3\alpha}$. PGD_2, and PGI_2 (prostacylcin), as well as analogues and derivatives of such natural compounds (including the pharmaceutically acceptable esters and salts of such natural compounds and their analogues and derivatives), which have similar biological activities of either greater of lesser potencies.

2. "Enhancing the Chemical Stability"

The term "enhance / enhancing the chemical stability" is recited in claim 1 of both Schneider Patents. Alcon construes the term to mean, "to add sufficient polyethoxylated castor

oil to an aqueous composition, and thus improve the chemical stability of a prostaglandin therein, so that the composition is commercially viably storage stable." (Alcon Markman Hr'g Presentation at Slide 65 (Apr. 27, 2011).) Defendants define the term to mean, "to increase or increasing the ability of the prostaglandin to resist chemical change (as distinguished from merely increasing the physical stability of the prostaglandin or composition.)" (Def.s' Opening Br. at 8.)

Defendants definition of the term is in line with what our educated lay sensibilities tell us the term means. Indeed, it is simply another way of saying the same thing. "To enhance" means the same thing to us as "to increase ability." "Stability" is the opposite of "change,"and "resist" connotes "opposition." Therefore, "enhancing stability" is the same thing as "increasing ability to resist change."

Defendants, however, expand on this common language definition and incorporate a parenthetical aspect to ensure that the term is limited to "chemical" rather than "physical" stability. Alcon does not dispute that the term implicates only "chemical" stability, therefore we deem it appropriate to limit the term's meaning within the construction, as Defendants propose. (See Alcon Rebuttal Br. at 8 ("About that, there is no disagreement; that is what the claim terms says."); see also Markman Hr'g Tr. ("[W]e've been accused of attempting to import physical stability limitations by the use of this chemically viable term. That is not our intent and we're not advocating that.").)

Alcon argues that the purpose of its construction is "to make clear how stable [the composition] has become." (Markman Hr'g Tr. at 161: 17-18 (Apr. 27, 2011). In doing so, Alcon looks to the Background section of the patents which describes the general problem to be

addressed by the inventions. The patents both state: "[w]hat is needed is a commercially viable, storage-stable prostaglandin composition." ('287 patent, col. 1, ll. 40-41 (Pl.'s Ex. 1); '062 patent, col. 1, ll. 48-49 (Pl.'s Ex. 2).) Accordingly, Alcon argues, the level of chemical stability contemplated by claim 1 of the patents is the level at which the composition is commercially viably and storage-stable.

Although we recognize that Phillips directs that the claims of a patent "must be read in view of the specification, of which they are part," 415 F.3d at 1315, and that the general object of the claim in this case is undoubtedly in line with the stated object of the patent, we decline to import the general "commercial" purpose of the invention as a specific limitation for the claims. See Yoon Ja Kim v. ConAgra Foods, Inc., 465 F.3d 1312, 1319 (Fed. Cir. 2006) ("The mere fact that one object of the invention is to produce a slow acting antioxidant which is functional throughout the entire manufacturing process does not mean that this particular feature was adopted as a limitation in each claim of the patent."); see also, E-Pass, 343 F.3d at 1370 ("The court's task is not to limit claim language to exclude particular devices because they do not serve a perceived 'purpose' of the invention.") In the present case, importing the "commercially viably storage stable" limitation into the claim would ground the meaning of the term as much in the fickle whims of the market as in the language of the patent itself.

Accordingly, we find that nothing in the intrinsic evidence suggests that the patentee, either by express lexicography or by implication, intended to take the term out of the plain meaning. The proper construction of the term, therefore, is: "to increase or increasing the ability of the prostaglandin to resist chemical change (as distinguished from merely increasing the physical stability of the prostaglandin or composition.)"

3. "Therapeutically Effective Amount of Prostaglandin"

The term "therapeutically-effective amount of prostaglandin" is recited in independent claim 1 of the '287 patent and claim 12 of the '062 patent. Defendants contend that the term is indefinite. Alcon argues that the term has a plain and ordinary meaning, which we should adopt, and that we should defer any consideration of Defendants' indefiniteness arguments for a later date. Defendants do not oppose deferring the indefiniteness issue until the time of trial. (Markman Hr'g Tr. at 173: 13-15 (Apr. 27, 2011).)

We find that the indefiniteness issue is best decided at trial and defer consideration on it until that time. See CSB-System Intern. Inc. v. SAP America, Inc., No. 10–2156, 2011 WL 3240838, at n.16 (E.D.Pa. Jul. 28, 2011) ("[T]he weight of the jurisprudence disfavors indefiniteness determinations at the Markman stage of patent litigation) (citing Waddington N. Am., Inc. v. Sabert Corp., No. CIV.A.09–4883, 2010 WL 4363137, at *2 (D.N.J. Oct. 27, 2010); Intergraph Hardware Techs. Co. v. Toshiba Corp., 508 F.Supp.2d 752, 773 n. 3 (N.D. Cal.2007) ("[The] indefiniteness argument is inappropriate at the claim construction stage."); Pharmastem Therapeutics, Inc. v. Viacell Inc., No. CIV.A.02–148, 2003 WL 124149, at *1 n. 1 (D. Del. Jan. 13, 2003) ("[T]he court will not address the defendants' indefiniteness argument at [the Markman stage].... At present, the Court is merely holding that the claim is sufficiently definite to survive claim construction."). We recognize, however, as our sister court of this district recently did in CSB-System International, that "this scenario creates somewhat of a quandary since the terms are clearly disputed and require a construction upon which the parties may proceed throughout the remainder of this litigation." 2011 WL 3240838 at *18. Accordingly, we shall set forth a brief discussion of the term so as to guide the litigation, without prejudice to

Defendants' raising an indefiniteness defense at the appropriate time.

Alcon proposes discordant constructions for the term. In its opening brief, Alcon states that "[t]he term 'a therapeutically-effective amount' of a . . . prostaglandin . . . means what it says: an amount of prostaglandin effective to promote a desired therapeutic effect." (Pl.'s Opening Br. at 13.) However, the rebuttal brief states that, "'a therapeutically effective amount of prostaglandin' is an amount of a prostaglandin sufficient to promote a therapeutic effect." (Pl.'s Rebuttal Br. at 10.) The definition Alcon provided at Markman hearing mirrors this latter version. (Markman Hr'g Tr. at 171:8-11.) The subtle differences between the constructions Alcon provides are important. Notably, the word "effective" as used in the opening brief, and the term "effect," as used in the rebuttal brief and at the Markman hearing, have different connotations such that Alcon's definition of "an amount sufficient to confer a therapeutic effect" is not simply a plain-language restatement of "a therapeutically-effective amount." The widely and commonly accepted meaning of "effective amount" implies an amount necessary to achieve an *intended*, *expected* or *desired* result. Alcon clearly recognized this when, in their opening brief, they included the word "desired" in their definition. Id. at 1278. On the other hand, and "amount that has a therapeutic effect" implies simply *any* therapeutic result or consequence. Clearly, the two definitions are not the same—an amount can produce a therapeutic effect without being therapeutically effective.

The claim in the present case uses the term "therapeutically *effective* amount." We find that this term is in line with the construction Alcon provides in its opening brief. The definition Alcon provides in its rebuttal brief and at the Markman hearing, however, is incongruous with the commonly understood meaning of the terms used in the claims, as explained above. Though

we take occasion to outline these thoughts so that we may narrow the issues for the benefit of the parties prior to trial, we decline to adopt a construction other than that which stated in the patents, and we defer further consideration of the term until the appropriate time at trial.

4. "Aqueous Composition"

The term "aqueous composition" is recited in claim 1 of the '287 patent and claims 1 and 12 of the '062 patent. Alcon argues that the term should be construed as "a composition in which the prostaglandin is in the aqueous phase." (Alcon Markman Presentation at slide 73 (Apr. 27, 2011).) Defendants construe the term as "all of the components collectively in a formulation containing a quantifiable amount of water in one or more liquid phases." (Def.s' Rebuttal Br. at 27.) We find that Defendants' construction matches the ordinary meaning of the term that has not been altered by the patent either expressly or by implication.

The parties disputed a similar term— "aqueous ophthalmic composition"—with respect to the Chowhan Patents as discussed above. We began our discussion of that term by noting that, as laymen considering the common meaning of the terms, we understood that "aqueous ophthalmic composition" encompassed a water-based formulation containing components directed toward use in the eye. However, in that case, there were specific and express teachings in the patent that the borate-polyol complex had to be in a *solution*, thereby altering the abstract meaning of the term as we understood it. (See supra at 21.)

Unlike the Chowhan Patents, the Schneider Patents lack any specific teachings that require the prostaglandin to be in solution in water Alcon contends. There is no language in the Schneider Patents that certain components must exist in specific phases within the composition. Instead, Alcon points to the "essence" of the invention—which, it argues, was finding a way to

dissolve prostaglandins in water without compromising the storage stability of the drug—to support its contention that the specification requires a specific meaning for "aqueous composition" in this case. (Pl.'s Opening Br. at 17.) As we explained with regard to "enhancing the chemical stability," above, the ultimate object of the invention is not automatically imported as a limitation into each of the claims. (See supra at 28.) Similarly, we find that it would be inappropriate to import the invention's "essence" as implying specific lexicography for a claim term. Accordingly, we find that Alcon's construction is improper.

Defendant's construction, on the other hand, comports with what our educated lay sensibilities suggest "aqueous composition" means. Defendants' expert confirms that the construction "all of the components collectively in a formulation containing a quantifiable amount of water in one or more liquid phases" is consistent with how a person of ordinary skill in pharmacy, analytical chemistry, organic chemistry, or chemical engineering, would understand the term "aqueous composition" as used in the Schneider Patents means. (Decl. of Paul Greico, Ex. to Def.s' Rebuttal Br., Doc. No. 163 at ¶ ¶ 23-24.) We therefore adopt this definition.

IV. CONCLUSION

The Court adopts the constructions set forth in this memorandum for the disputed terms of the '287, '062, '497 and '253. An appropriate order follows.